TENNESSEE CONTROLLED SUBSTANCE COLLECTION DATABASE

DATA COLLECTION MANUAL

Effective: May 21, 2013

Optimum Technology, Inc.

Contact Information: 866-683-9771

tnrxreport@otech.com

TABLE OF CONTENTS

Contents

SUBMITTING THE DATA 3
REPORTING PROCEDURES and FILE TYPES 3
Website Upload/Prescription File Uploads 3
Uploading your file 4
CD-ROM, CD-R, CD-RW, DVD or 3 1/2" Diskette (A transmittal form must accompany all submissions.) 4
FTPs Transfer - Dispenser – FTPs account 4
Zero Reports 5
ALTERNATIVE REPORTING METHODS 5
Manual Entry 6
ONLINE DATA REPORTING WEB SERVICE 6
Online Data Reporting Web Service 6
Web Service Definition (WSDL) 7
Sample Response (PMP Fatal Error Return) 11
Transaction Response 12
ERRORS and CORRECTIONS 12
Error Correction 12
Rejections 13
Viewing your Errors and File Upload Status: 14
View File Upload Errors 14
PRESCRIPTION CORRECTIONS 14
EXEMPTIONS FROM REPORTING 15
Exemptions 15
WHAT DATA IS MANDATORY, WHAT IS OPTIONAL? 15
PASSWORDS AND SIGN-IN INFORMATION: 19
PRESCRIPTION DATA AND REPORTING REQUIREMENTS 19
What is the NDC Code? 19
What drugs should be reported? 19
How often should I submit data? 19
How are compounded prescriptions to be recorded? 19

Why is the system rejecting the input metric quantity? 20
What should the dispenser do if dispenser meets one of the conditions to be considered exempt from reporting? 20
I received a Delinquency Letter; what should I do? 20
FILE ISSUES AND ERROR CORRECTIONS 20
What should the filename be? 20
What does the file status 'Pending' mean? 20
I do not work with a software vendor; how should I submit controlled substance data? 20
I accidentally sent the incorrect reporting period. Should the file be deleted? 21
What should I do if my file was rejected? 21
How do I know if my file uploaded? 21
I accidentally submitted incorrect information. Can I delete a record/entry? 21
Why are there no menus displayed on the web page? 21
How do I fix “duplicate” error messages? 21
OTHER QUESTIONS 22
How do I setup an FTP account? 22
How should the address for a patient not from the U.S. be entered to be accepted by the program? 22
ASSISTANCE AND SUPPORT 22
Addendum 1: Program Transmittal Form 23
Addendum 2: Universal Claim Form 24
Addendum 3: Dispenser or Waiver Request 25
Addendum 4: Correcting/Deleting a Previously Submitted Prescription 26
Addendum 5: Zero Report 30

TENNESSEE CONTROLLED SUBSTANCE DATABASE

In accordance with Tennessee Annotated Code §53-10-301*, et seq*., the Tennessee Department of Health has established a program to monitor the prescribing and dispensing of Schedules II, III, IV & V controlled substances. The program requires that certain information about controlled substances which are dispensed be submitted to the database. Information must be submitted at least once every 7 days for all controlled substances dispensed during the preceding 7-day period.

SUBMITTING THE DATA

Dispensers will report the required dispensing information as defined in Tenn. Code Ann. §53-10-305 to Optimum Technology, Inc. (Optimum), a private contractor, which will collect all data and manage the technical aspects of the program.

Toll-free number for Optimum: 866-683-9771

Email for technical assistance: **tnrxreport@otech.com**

Such reporting without individual authorization by the patient is allowed under HIPAA, 45CFR § 164.512, paragraphs (a) and (d). The Tennessee Board of Pharmacy is a health regulatory agency and Optimum is acting as an agent of Tennessee Board of Pharmacy in the collection of this information.

Attention: Effective April 1, 2012 files must be in ASAP 2009 v4.1 format. Files not in this format will be rejected by the system.

All transactions must be submitted at least once every 7 days for all of the controlled substances dispensed the preceding 7-day period. Tenn. Code Ann. §53-10-305

REPORTING PROCEDURES and FILE TYPES

All controlled substances contained in Schedules II, III, and IV which are dispensed and Schedule V controlled substances identified by the Controlled Substance Monitoring Database Committee as demonstrating a potential for abuse must be reported. Tenn. Code Ann. §53-10-305

All dispensers licensed by the State of Tennessee that dispense Schedules II-V controlled substances are required to submit the information by one of the following data submission options.

Website Upload/Prescription File Uploads

The user must use the login credentials provided to sign into the user account at the following website: **www.tnrxreport.com**. You may also register for account access at this website.

This secure website address is provided for uploading data to Optimum, which utilizes 256-bit encryption. Dispensers are able to access the secure website via a web browser.

Please inform your software vendor that you will need to be able to upload your data in the ASAP 2009 v4.1 format as a .DAT or .TXT file.

Your file will need to be named according to the following rules: your DEA number, the date submitted, followed by **.DAT** or **.TXT**

Therefore, if your DEA number is *AB1234567* and you are submitting on April 1, 2013, the file name would look like this: ***AB1234567040113.dat*.**

Please name your files accordingly when submitting your controlled substance information. This will assist you with keeping accurate records of the information reported to Optimum and will assist with locating this information in a timely and efficient manner, should this be necessary.

Uploading your file

1. Create a file using your pharmacy software and save it to your computer's hard drive.
2. Login to www.tnrxreport.com with username and password.
3. Go to the **Data Collection menu** > Choose **File Upload from the dropdown menu.**
4. **Click Browse** to locate your file.
5. Highlight the File, then **Click Open** (the file will populate in the File Name field.)
6. **Click Upload** to send the file to Optimum.
7. You will receive confirmation via the web page that your file was successfully submitted and will be processed by the batch processor within 24 hours.
8. Once the batch processor has processed the file you will be notified via the message center and email (if a valid email has been provided.)

You may view all uploaded files, and their status, on the "View Uploaded files" tab on the File Upload page. This page will show a history of all files submitted to the program, their status, and any errors contained within the file. Corrections may also be made via the View Uploaded Files tab. (*See the section "Errors and Corrections".)*

CD-ROM, CD-R, CD-RW, DVD or 3 1/2" Diskette (A transmittal form must accompany all submissions.)

A Program Transmittal Form (Addendum 1) should accompany external media submissions. The dispenser should make copies of the enclosed, blank Program Transmittal Form for future use or print a blank form from **www.tnrxreport.com** . The dispenser may also wish to keep a copy of the completed form for its records.

This file must also contain an external media label, with the following information: Dispenser*/Submitter Name, DEA number, and the number of prescriptions.*

These media forms must be mailed to:

Optimum Technology, Inc.
Attn: Data Collection
100 E Campus View Blvd
Suite 380
Columbus, OH 43235

FTPs Transfer - Dispenser – FTPs account

Chain Pharmacies and Community Pharmacies with multiple facilities may submit one data transmission on behalf of all of their facilities. In fact, the program prefers that chain pharmacies and community pharmacies with multiple facilities submit one transmission with the data for all of their facilities. They may do so utilizing the FTP procedure. *If they wish to do so, during registration they must appoint one contact person for all of their data submissions.*

Chain pharmacies should seek direction from their corporate offices concerning how their data will be reported. Corporate offices and their software vendors should register at **www.tnrxreport.com**, as

an FTP Up-Loader, to obtain a user ID and password. The host name for transfer is **www.tnrxreport.com.** Optimum only supports FTPs and SFTP transmissions. Login credentials will be emailed to the email address listed in the registration within 24-48 business hours.

(Zero Reports via FTPs can ONLY be submitted in the ASAP 2009/v4.1. Please see Addendum 5 titled 'zero reports' for additional information.)

Zero Reports

If a dispenser does not dispense any Schedule II-V prescriptions during a reporting period, a "zero" report should be submitted. This may be done via the prescription upload website: **www.tnrxreport.com** under the Data Collection menu.

To Access the Zero Reporting screen in the data collection portal:

1. Login to **www.tnrxreport.com** with your username and password.
2. Go to the **Data Collection menu**.
3. Click on the option **Upload Pharmacy Zero Report**.
4. Select the reporting period for zero report submission.
5. Click **Submit**.

Chain pharmacies should seek direction from their corporate offices concerning how their data (zero reports) will be submitted. *Zero reports can only be submitted via a web account specific to the dispensers DEA # or via FTPs in ASAP 2009/v4.1.*

Zero reports via FTPs transmission in ASAP 4.1 format:

The Zero Report standard is a complete transaction and includes all fields required by the CSMD program according to the states requirements. Transaction Headers and Trailer Segments are completed as they would be with a normal controlled substance report. All required detail segments are to be sent and left blank with the exception of the PAT07; PAT08; and DSP05. The segments should be completed accordingly: PAT07 = Report; PAT08 = Zero; DSP05 = Date report is sent.

ALTERNATIVE REPORTING METHODS

If the dispenser does not have an automated recordkeeping system or can show that electronic reporting by any of the above means creates an undue hardship, a waiver may be granted by the Committee that would allow the dispenser to submit in one of the following alternative formats. The application for the waiver must be completed and submitted to the CSMD Administrator. Please begin reporting in one of the alternate approved methods. Waiver is subject to approval by the Controlled Substance Monitoring Database Committee. (See Attachment 3)

Manual Entry

A sample of the information required to fill out this form is attached (Attachment 2).

1. **To Access the UCF Manual Entry screen in the data collection portal:**
   1. Login to www.tnrxreport.com with your username and password
   2. Hover over the **Data Collection Menu**
   3. Click on **Manual Entry**
   4. As explained in the **'WHAT DATA IS MANDATORY, WHAT IS OPTIONAL'** section, the dispenser must have at least the mandatory data available to enter manual prescriptions.
   5. To enter another prescription, please repeat steps two and three. Failure to do so will create flawed/incorrect prescription records.
2. **The second alternative form utilizes the Universal Claim Form** (Attachment 2) which will be mailed to Optimum Technology after the dispenser has been granted a waiver by the Committee.

ONLINE DATA REPORTING WEB SERVICE

Online Data Reporting Web Service

A secured web service (https://www.webservices.tnrxreport.com/datareporting.asmx) is used to transmit controlled substance prescription information via the secured web service requires an internet connection with 128-bit encryption Secure Socket Layer (SSL).

The web service provides the following method to submit the prescription data.

Method Name	Description
SubmitTransaction	The web method validates processes and uploads the submitted prescription data. In case of any error, it will return the error message.

Request:

Field Name	Type	Description
Username	Text	Authorized user name
ASAPBlock	Text	Complete ASP2009 Transaction
Password	Text	Password

Response:

Field Name	Type	Description
TransactionID	Number	Unique Identifier for the transaction
TransactionStatus	Number	Processed(1) / Rejected (0)
FatalError	Boolean	Yes (1) / No (0)
ErrorMessage	Text	Message describing the error

Web Service Definition (WSDL)

The following Web Service description is used for reporting prescriptions in real-time to Tennessee's PMP.

Web Service Description

```
<?xml version="1.0" encoding="UTF-8"?>
<wsdl:definitions xmlns:wsdl="http://schemas.xmlsoap.org/wsdl/"
targetNamespace="https://www.tnrxreport.com/webservices/"
xmlns:soapenc="http://schemas.xmlsoap.org/soap/encoding/" xmlns:http="http://schemas.xmlsoap.org/wsdl/http/"
xmlns:tm="http://microsoft.com/wsdl/mime/textMatching/" xmlns:soap="http://schemas.xmlsoap.org/wsdl/soap/"
xmlns:tns="https://www.tnrxreport.com/webservices/" xmlns:mime="http://schemas.xmlsoap.org/wsdl/mime/"
xmlns:soap12="http://schemas.xmlsoap.org/wsdl/soap12/" xmlns:s="http://www.w3.org/2001/XMLSchema">
 <wsdl:types>
  <s:schema targetNamespace="https://www.tnrxreport.com/webservices/" elementFormDefault="qualified">
   <s:element name="SubmitTransaction">
    <s:complexType>
     <s:sequence>
    <s:element name="PMPT" type="tns:PMPTransaction" maxOccurs="1" minOccurs="0"/>
   </s:sequence>
  </s:complexType>
 </s:element>
 <s:complexType name="PMPTransaction">
  <s:sequence>
   <s:element name="Username" type="s:string" maxOccurs="1" minOccurs="0"/>
   <s:element name="ASAPBlock" type="s:string" maxOccurs="1" minOccurs="0"/>
   <s:element name="Password" type="s:string" maxOccurs="1" minOccurs="0"/>
  </s:sequence>
 </s:complexType>
 <s:element name="SubmitTransactionResponse">
```

```
 <s:complexType>
  <s:sequence>
   <s:element name="SubmitTransactionResult" type="tns:PMPTransactionResult" maxOccurs="1" minOccurs="0"/>
  </s:sequence>
 </s:complexType>
</s:element>
<s:complexType name="PMPTransactionResult">
 <s:sequence>
  <s:element name="TransactionID" type="s:string" maxOccurs="1" minOccurs="0"/>
  <s:element name="TransactionStatus" type="s:string" maxOccurs="1" minOccurs="0"/>
  <s:element name="FatalError" type="s:string" maxOccurs="1" minOccurs="0"/>
  <s:element name="ErrorMessage" type="s:string" maxOccurs="1" minOccurs="0"/>
 </s:sequence>
</s:complexType>
<s:element name="PMPWSSoapHeader" type="tns:PMPWSSoapHeader"/>
 <s:complexType name="PMPWSSoapHeader">
  <s:sequence>
   <s:element name="Version" type="s:string" maxOccurs="1" minOccurs="0"/>
   <s:element name="State" type="s:string" maxOccurs="1" minOccurs="0"/>
  </s:sequence>
```

```
  <s:anyAttribute/>
 </s:complexType>
</s:schema>
</wsdl:types>
<wsdl:message name="SubmitTransactionSoapIn">
 <wsdl:part name="parameters" element="tns:SubmitTransaction"/>
</wsdl:message>
<wsdl:message name="SubmitTransactionSoapOut">
 <wsdl:part name="parameters" element="tns:SubmitTransactionResponse"/>
</wsdl:message>
<wsdl:message name="SubmitTransactionPMPWSSoapHeader">
 <wsdl:part name="PMPWSSoapHeader" element="tns:PMPWSSoapHeader"/>
</wsdl:message>
<wsdl:portType name="PMPWSSoap">
 <wsdl:operation name="SubmitTransaction">
  <wsdl:input message="tns:SubmitTransactionSoapIn"/>
```

```
 <wsdl:output message="tns:SubmitTransactionSoapOut"/>
 </wsdl:operation>
</wsdl:portType>
<wsdl:binding name="PMPWSSoap" type="tns:PMPWSSoap">
 <soap:binding transport="http://schemas.xmlsoap.org/soap/http"/>
 <wsdl:operation name="SubmitTransaction">
  <soap:operation style="document" soapAction="https://www.tnrxreport.com/webservices/SubmitTransaction"/>
  <wsdl:input>
   <soap:body use="literal"/>
  </wsdl:input>
  <wsdl:output>
   <soap:body use="literal"/>
   <soap:header message="tns:SubmitTransactionPMPWSSoapHeader" use="literal" part="PMPWSSoapHeader"/>
  </wsdl:output>
 </wsdl:operation>
</wsdl:binding>
<wsdl:binding name="PMPWSSoap12" type="tns:PMPWSSoap">
 <soap12:binding transport="http://schemas.xmlsoap.org/soap/http"/>
 <wsdl:operation name="SubmitTransaction">
  <soap12:operation style="document" soapAction="https://www.tnrxreport.com/webservices/SubmitTransaction"/>
  <wsdl:input>
   <soap12:body use="literal"/>
  </wsdl:input>
  <wsdl:output>
   <soap12:body use="literal"/>
   <soap12:header message="tns:SubmitTransactionPMPWSSoapHeader" use="literal" part="PMPWSSoapHeader"/>
  </wsdl:output>
 </wsdl:operation>
</wsdl:binding>
<wsdl:service name="PMPWS">
 <wsdl:port name="PMPWSSoap" binding="tns:PMPWSSoap">
  <soap:address location="https://www.webservices.tnrxreport.com/datareporting.asmx"/>
 </wsdl:port>
 <wsdl:port name="PMPWSSoap12" binding="tns:PMPWSSoap12">
  <soap12:address location="https://www.webservices.tnrxreport.com/datareporting.asmx"/>
 </wsdl:port>
```

```
</wsdl:service>
</wsdl:definitions>
```

Sample Request:

```
POST /DataReporting.asmx HTTP/1.1
Host: www.webservices.tnrxreport.com
Content-Type: text/xml; charset=utf-8
Content-Length: length
SOAPAction: "https://www.tnrxreport.com/webservices/SubmitTransaction"
<?xml version="1.0" encoding="utf-8"?>
<soap:Envelope xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema" xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/">
<soap:Body>
<SubmitTransaction xmlns="https://www.tnrxreport.com/webservices/">
<PMPT>
<Username>myusername</Username>
<ASAPBlock> TH*4.1*857463*01**20130115*1410*P**~~
IS*7564*Pharmacy Name*this is a sample upload~
PHA***PharmacyDEANumber*PharmacyName*Address1*Address2*City*State*Zip*PhoneNumber*ContactName*StoreNumber~
PAT***IDofPatient****LastName*FirstName****Address1*Address2*City*State*Zip*PhoneNumber*DOB*GenderCode*SpeciesCode*~
DSP*ReportingStatus*RxNumber*DateWritten*RefillsAuthorized*DateFilled*RefillNumber*ProductIDQualifier*ProductID*QtyDispensed*DaysSupply**********~
PRE**PractitionerDEANumber***LastName*FirstName**~
TP*6~
TT*857463*8~
</ASAPBlock>
<Password>mypassw0rd</Password>
</PMPT>
</SubmitTransaction>
</soap:Body>
</soap:Envelope>
```

Sample Response

```
HTTP/1.1 200 OK
Content-Type: text/xml; charset=utf-8
Content-Length: length
<?xml version="1.0" encoding="utf-8"?>
<soap:Envelope xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema" xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/">
<soap:Body>
<SubmitTransactionResponse xmlns="https://www.tnrxreport.com/webservices/">
<SubmitTransactionResult>
<TransactionID>99999999</TransactionID>
<TransactionStatus>1</TransactionStatus>
<FatalError>0</FatalError>
<ErrorMessage></ErrorMessage>
</SubmitTransactionResult>
</SubmitTransactionResponse>
</soap:Body>
</soap:Envelope>
```

Sample Response (PMP Fatal Error Return)

```
HTTP/1.1 200 OK
Content-Type: text/xml; charset=utf-8
Content-Length: length
<?xml version="1.0" encoding="utf-8"?>
<soap:Envelope xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xmlns:xsd="http://www.w3.org/2001/XMLSchema"
xmlns:soap="http://schemas.xmlsoap.org/soap/envelope/">
<soap:Body>
<SubmitTransactionResponse xmlns="https://www.tnrxreport.com/webservices/">
<SubmitTransactionResult>
<TransactionID>0</TransactionID>
<TransactionStatus>1</TransactionStatus>
<FatalError>1</FatalError>
<ErrorMessage>The processing failed due to the invalid ASAP version. Please try again.</ErrorMessage>
</SubmitTransactionResult>
</SubmitTransactionResponse>
</soap:Body>
```

```
</soap:Envelope>
```

Transaction Response

The TNCSMD data collection web service will acknowledge the transaction with TransactionID, TransactionStatus and Success or Failure notification.

- TransactionID – Unique Transaction Identifier
  - <TransactionID>99999999</TransactionID>
- TransactionStatus – Status of the transaction – Processed or Rejected
  - <TransactionStatus>1</TransactionStatus>
- Success
  - <FatalError>0</FatalError>
  - <ErrorMessage></ErrorMessage>
- Failure
  - <FatalError>1</FatalError>
  - <ErrorMessage>The processing failed due to the invalid ASAP version. Please try again.</ErrorMessage>

ERRORS and CORRECTIONS

Error Correction

Pharmacies will be notified of errors contained in prescription drug reports via a daily error report sent to the e-mail address on record.

The error report file name will be in the following format:

- <DEANumber or Username>_ErrorReport_<MMddyyyy>.csv

  [e.g. BC6459398_ErrorReport_04022013.csv]

The sample error report will look like the following:

ErrorMessage	Data
PRE03,DEA Number Suffix,Error,'General Surgery', value exceeds the length allowed; The allowed length for the field is 7;	DSP|00|1494185|20130110|0|20130110|0|01|00406324301|30.0000|7|01|01|02|||3|20130110|||; PHA|1740295765|4435536|BW7777777|WALGREENS STORE|Addess1|Address2|Columbus|OH|373034907|4237457749||05790; PRE|1982684361|AC2222222|General Surgery||Cox|Charles|; AIR|||||||||||;
:Duplicate Prescription.;	DSP|00|7355|20130103|0|20130103|0|01|10702002510|45.0000|30|01||||1||||; PHA|||MS8888888|General Pharmacy|Pharmacy Address||Columbus|OH|99999|6153253394|LastName, FirstName|; PRE||MS9999999|||||; AIR|OH||OH||||||||;
more than one patients found for previously submitted prescription(s) or refill(s)	DSP|00|0111442|20121017|1|20130111|3|01|00591038501|60.0000|30|01||||4||||
Patient details does not match with previously submitted prescription(s) or refill(s)	DSP|00|18152|20121228|0|20121228|0|01|00527144510|60.0000|30|01||||99||||

TNCSMD data collection offers following methods to correct the error

1. Re-transmit with corrected data
2. Log into TN data collection and manually correct them

Rejections

The CSMD application will validate each file submitted, record by record, and will reject those records which do not meet the validation requirements. If there are a limited number of errors, only those records with errors will be rejected. The user will be notified via email & the message center of the status of the file, and the errors contained within.

If the records in a file do not meet the required data specifications, the entire file may be rejected. **In this instance, the submitter will be notified via email and/or the 'Message Center' of the reason for this failure.** (A valid email address is required for email notification.)

Optimum is not authorized to modify any data; therefore, the dispenser will be required to correct these errors through the website or resubmit the entire file, if necessary.

Viewing your Errors and File Upload Status:

The Data Collection Portal allows all users to login and view the status of their Uploaded Files. A history of all files submitted to the program can be viewed on the View Uploaded Files tab under the Data Collection Menu. This page will also show the user any errors associated with a particular file, and will allow the user to make corrections to these errors through the website. Please follow the details below to view your uploaded files and any errors associated with those files.

View File Upload Errors

1. Login to **www.tnrxreport.com** with your username and password.
2. Go to the **Data Collection Menu** > Click on **File Upload.**
3. Click on the **View Uploaded Files tab**. This will display a history of all files submitted.
4. Click on the File containing errors that you wish to correct.
5. Click on each individual error to see a detailed description at the bottom of the page.

PRESCRIPTION CORRECTIONS

There are two options to correct the data as detailed below.

1. Correct the data in your retail RX software; regenerate the file and upload the data.
    a. Please note this process may result in duplicate records as a portion of the records originally submitted were accepted. **The duplicate records require no action on the part of the pharmacy or dispenser**.
    b. *You may also choose to correct only those records that were rejected and create a separate file to submit.*
2. Correct the data online via the Data Collection Portal. This type of correction is manually performed and makes sense when there are minimal errors.
    a. Login to **www.tnrxreport.com** with your username and password.
    b. Go to the **Data Collection Menu** > Click on **File Upload.**
    c. Click on the **View Uploaded Files tab**. This will display a history of all files submitted.
    d. Click on the File containing errors that you wish to correct.
    e. To the right of each error, click on the **paper/pencil icon**. You will then be shown a Prescription correction screen.
    f. Correct the fields indicated, click the authorization checkbox, and then Click Save.
    g. You will receive an online confirmation that your file was successfully saved.

Prescription Maintenance

For security purposes, data cannot be deleted by Optimum once it is submitted to the program. To remedy this situation, go to the Prescription Maintenance page under the Data Management menu. Search for the RX by prescription number, Prescriber DEA, Date filled or any combination of these criteria. You can then update the information by clicking on the prescription in question, correcting the information, checking the authorization check box, and clicking 'save'. To delete the prescription, click on the prescription in question, check the authorization checkbox, and click 'delete'.

Test Run Upload Feature

This feature is provided to assist the user with identifying errors within a file, prior to submitting the information to Optimum for reporting purposes. It is located under the Data Collection menu within the Data Collection website. The feature can be used for any type of file that it is submitted directly through the www.tnrxreport.com website.

The process is similar to submitting your completed file, but will allow the user to see any errors, and correct those errors prior to your submission to the State reporting agency.

If you have attempted to submit your file, and are receiving rejection notices or extensive errors, please utilize this function. This function may also assist your software vendor with helping to identify any corrections that may be needed related to software or the format of your file.

EXEMPTIONS FROM REPORTING

Exemptions

- Dispensing of manufacturer's samples
- Any drug dispensed by a licensed health care facility; provided that the quantity dispensed is limited to an amount adequate to treat the patient for a maximum of forty-eight (48) hours.
- A drug administered directly to a patient
- Dispensing within an appropriately licensed narcotic maintenance treatment program by the United States Drug Enforcement Administration.
- A drug dispensed by a licensed veterinarian if the quantity dispensed is limited to an amount adequate to treat an animal for a maximum of 48 hours.

If you wish to submit a request for exemption from reporting please fill out the attached exemption/waiver request form and mail to:

Department of Health Related Boards
Tennessee Board of Pharmacy
Controlled Substance Database
665 Mainstream Drive
Nashville, TN 37243

Or submit by FAX to (615) 253-8782
The exemption request must be approved by the Controlled Substance Monitoring Database Advisory Committee before it is effective.

WHAT DATA IS MANDATORY, WHAT IS OPTIONAL?

Controlled Substance Schedule II - Summary of ASAP 2009 v4.1 Data Elements

Note: ASAP Version 4 • Release 1 is used

Visit www.asapnet.com to purchase a complete implementation guide for all ASAP standards in the online bookstore.

Ref. Code	Data Element Name	Format	Attributes*

Ref. Code	Data Element Name	Format	Attributes*
HEADER SEGMENTS			
TH TRANSACTION HEADER – (TH01-TH09)			**Required Data**
TH01	Version/Release Number	4.1	Yes
TH02	Transaction Control Number	See TT01; GUID is recommended	Yes
TH05	Created Date	CCYYMMDD	Yes
TH06	Creation Time	HHMMSS or HHMM	Yes
TH07	File Type	P = Production; T = Test	Yes
TH09	Segment Terminator Character	Examples: ~~ or || or ::	Yes
IS INFORMATION SOURCE – (IS01-IS03)			
IS01	Unique Information Source	(Ex: Phone number)	Yes
IS02	Information Source Entity Name	Pharmacy Name	Yes
PHA DISPENSING PHARMACY – (PHA01-PHA12)			
PHA03	DEA Number		Yes
DETAIL SEGMENTS			
PAT - PATIENT DETAIL SEGMENT – (PAT01-PAT23)			
PAT07	Last Name		Yes
PAT08	First Name		Yes
PAT12	Address Information – 1		Yes
PAT14	City Address		Yes
PAT15	State Address		Yes
PAT16	ZIP Code Address	"00000" Non-US	Yes
PAT18	Date of Birth	CCYYMMDD	Yes
PAT19	Gender Code	F-Female, M-Male, U-Unknown	Yes
DSP - DISPENSING DETAIL SEGMENT - REQUIRED			
DSP01	Reporting Status	"00" New record; "01" Revise; "02"	Yes

Ref. Code	Data Element Name	Format	Attributes*
		Void	
DSP02	Prescription Number		Yes
DSP03	Date Written	CCYYMMDD	Yes
DSP04	Refills Authorized		Yes
DSP05	Date Filled	CCYYMMDD	Yes
DSP06	Refill Number	0 = indicates original dispensing; 01-99 is the refill number	Yes
DSP07	Product ID Qualifier	"01" NDC# or "06" compound	Yes
DSP08	Product ID	NDC# or "99999999999" for compound; If a compound the CDI segment is required	Yes
DSP09	Quantity Dispensed	Metric decimal format	Yes
DSP10	Days Supply		Yes
DSP11	Drug Dosage Units Code	"01" = Each (solid dosage units or indivisible packages) "02" = ml "03" = gm (values must be converted to liter/ mg equivalent)	Yes
DSP16	Classification Code for Payment Type	01 = Private Pay (Cash/Charge) 02 = Medicaid 03 = Medicare 04 = Commercial Insurance 05 = Military and VA 06 = Workers Compensation 07 = Indian Nations 99 = Other	Yes
PRE - PRESCRIBER DETAIL SEGMENT - REQUIRED			
PRE02	DEA Number		Yes
CDI - COMPOUND DRUG INGREDIENT DETAIL SEGMENT - If DSP07 = 06 all CDI segments required			

Ref. Code	Data Element Name	Format	Attributes*
CDI01	Compound Drug Ingredient Number	1st reportable ingredient is "1"; additional ingredients are incremented by 1.	SIT
CDI02	Product ID Qualifier	"01" = NDC#	SIT
CDI03	Product ID	As indicated in CDI02	SIT
CDI04	Compound Ingredient Quantity	Metric Decimal quantity	SIT
CDI05	Compound Drug Dosage Units Code	"01" # of units or "02" ml or "03" gm	SIT
AIR ADDITIONAL INFORMATION REPORTING - SITUATIONAL			
All Segments optional.			
SUMMARY SEGMENTS			
TP - PHARMACY TRAILER – REQUIRED			
TP01	**Detail Segment Count**	**Includes PHA; all Detail segments & TP segment**	**Yes**
TT01	**Transaction Control Number**	**Must match TH02**	**Yes**
TT02	**Segment Count**	**Total # of segments, including header and trailer segments**	**Yes**

*** AN-Alphanumeric, N-Numeric, D-Decimal, DT-Date, TM-Time (24hr clock)**

This page constitutes a summary of the required ASAP information for controlled substance reporting in TN; additional information must be obtained by purchasing an implementation guide at www.asapnet.org.

FREQUENTLY ASKED QUESTIONS:

PASSWORDS AND SIGN-IN INFORMATION:

Does my password expire?

For security purposes, passwords will expire every 180 days. You do not need to remember to update your password, as the system will automatically prompt you to change your password after 180 days.

Please note that your account will require you to update your password upon your initial sign-in. At this time, please answer the security questions provided. This will allow you to change/update your password during the evening/weekend hours.

I have entered my password numerous times, I am sure that it is correct? Why am I not able to access the system?

Please consider the type of information that you are attempting to locate. If you are attempting to submit records of your dispensed controlled substances, please go to the link 'Forgot my password'. If you have answered the security questions provided, you will be able to reset your password using this function.

If you are attempting to view patient information, or prescription history, please verify that you are accessing the CSMD instead of the data collection website.

PRESCRIPTION DATA AND REPORTING REQUIREMENTS

What is the NDC Code?

The National Drug Code is an 11 digit number used to identify drug strength, name, quantity etc. This number is found on the medication bottle.

What drugs should be reported?

All controlled substances contained in Schedules II, III, and IV which are dispensed and Schedule V controlled substances identified by the Controlled Substance Monitoring Database Committee as demonstrating a potential for abuse. Tenn. Code Ann. §53-10-305

How often should I submit data?

All transactions must be submitted at least every 7 days for the preceding 7 day period.

How are compounded prescriptions to be recorded?

Prescriptions compounded by the pharmacist and containing a controlled substance must be reported. To submit a compound controlled substance, the field DSP07 must indicate this by the value '06' for compound. Subsequently, DSP08 must then be reported as eleven "9's" or 99999999999. By reporting the value in DSP07 as '06', the CDI segment then becomes a mandatory or required segment.

The CDI segment will require that reportable controlled substances be reported in increments of 1 in field CDI01; the NDC code is reported as '01' in CDI02; and the NDC of those reportable ingredients is

provided in CDI03. The quantity is provided in metric decimal format in CDI04; and the Drug Dosage Units Code is reported in CDI05.

Why is the system rejecting the input metric quantity?

The metric quantity should be the number of metric units dispensed in metric decimal format. (Ex: 3.5)

What should the dispenser do if they meet one of the conditions to be considered exempt from reporting?

If exempt from reporting, please fill out the request for waiver or exemption (Addendum 3) and follow the instructions listed. This request must be approved by the Controlled Substance Monitoring Database Committee before it becomes effective.

I received a Delinquency Letter; what should I do?

If you received a Delinquency letter and would like to check the status of your data, please send an email to **tnrxreport@otech.com** with the following information (If you are unsure if your data was submitted, resubmit the time period in question. This request will take one day to process. Please provide:

1. Username
2. Reporting period(s) in question
3. DEA Number (if an FTP account is used for uploading reports)

If a confirmation is required, you may forward Optimum Tech's email response to the CSMD Administrator as confirmation your data was received.

FILE ISSUES AND ERROR CORRECTIONS

What should the filename be?

The filename should be the DEA number, followed by the date of submission, followed by **.dat or .txt.** Chain pharmacies may use the chain name, followed by the date of submission. The filename is less important than the contents of the file.

FTP users should be certain to differentiate files by adding to the filename before the **.dat or .txt** extension. This will ensure that the contents of the file are not overwritten. FTPs submissions with the same filename, submitted on the same day will overwrite the previously submitted file.

What does the file status 'Pending' mean?

Uploaded files will be processed twice during the evening/overnight (5:50 p.m. and 2:15 a.m.) by a batch processor, therefore they will be in 'Pending' status until the day following upload. You will receive notification via the message center and email, if you have supplied a valid email address. You can update this information in the My Accounts section of the website.

I do not work with a software vendor; how should I submit controlled substance data?

If you do not work with a software vendor, you will need submit a waiver form (Addendum 3) and then manually enter controlled substance data. To submit manually, go to Data Collection > Manual Entry -Complete all required fields and click save; no further action is required.

I accidentally sent the incorrect reporting period. Should the file be deleted?

If the wrong reporting period was uploaded, the file does not need to be deleted. Records that have already been processed by the system will be rejected as duplicate records. To remedy this issue, simply create a file with the correct reporting period and upload again.

What should I do if my file was rejected?

If your file was rejected, do a Test Run Upload. To do this, go to the Data Collection Menu > Test Run Upload and submit your file. The bottom of the screen will list file format problems. Missing or invalid fields should be corrected by your software vendor.

How do I know if my file uploaded?

1. Go to Data Collection > File Upload
2. Click on the View uploaded files tab
3. You will be able to view all files submitted

If you are not receiving email notifications, you will need to verify that your email address is listed *correctly*. Go to 'My Account' and enter your email address in the appropriate field, you will also receive file status notifications in the section of your account titled 'messages'.

An email will be sent within 14 hours confirming the file's processing status and any errors contained within that file.

(Please be sure to add the domain: otech.com to your safe sender's list within your email client. This will ensure that you receive communications from Optimum in a timely manner.)

I accidentally submitted incorrect information. Can I delete a record/entry?

The ASAP 2009 v4.1 formatting requirements allow for the following functions: 'new, revise or delete'. For those sending electronic files, please refer to DSP01 in the formatting table.

For users that submit manual entries, you are able to update previously submitted information. Please refer to the Addendum 4.

Even if you submit Files through FTP you can also make corrections/deletions through the website, please see the Addendum4 of this manual for further information.

Why are there no menus displayed on the web page?

If you are using Internet Explorer version 6.0 or higher, check which version you are currently using. Go to Help > About Internet Explorer. Verify that Compatibility mode is enabled. This can be found in the 'Tools' menu or your internet browser.

How do I fix "duplicate" error messages?

A duplicate error message displays when a data record is received and processed more than once. This normally occurs when a file is uploaded after correcting errors in your prescription software or when a file is uploaded twice in error for a different reporting period. *The duplicate records occurring as a result of duplicate file uploads require no action on the part of the dispenser.*

OTHER QUESTIONS

How do I setup an FTP account?

FTP account requests must be made via the registration page on **www.tnrxreport.com**. You will need to register for the job type 'FTP Up-Loaders'. You will receive login credentials at the email address indicated in your registration within 24-48 business hours.

How should the address for a patient not from the U.S. be entered to be accepted by the program?

Non-US zip codes or residents should have the value '00000' placed into the zip code category.

ASSISTANCE AND SUPPORT

Optimum is available to provide assistance and information to individual pharmacies, chain pharmacies, software vendors, and other entities required to submit data. Technical support is available to meet the program requirements. Questions concerning interpretation of technical and compliance matters may be referred to Optimum. Dispensers are advised to first contact their software vendor to obtain modifications and instructions on compliance and participation. Software vendors may also contact Optimum directly for assistance.

The Controlled Substance Monitoring Database Committee will act as the final interpreter of regulations. Unresolved disagreements between a dispenser and Optimum Tech will be resolved by the Committee.

Tennessee Data Collection:

For questions: call (866) 683-9771 or e-mail tnrxreport@otech.com

Addendum 1: Program Transmittal Form

Program Transmittal Form

File Name: _____ Date: _____

The file name should be the DEA number followed by .DAT (example: AB01123456.DAT)

Pharmacy/Dispenser Name: _____

DEA Number: _____

Number of Prescriptions in File: _____

Name of person submitting report: _____

Phone Number: _____ Fax Number: _____

External/diskette label must contain: Pharmacy/Submitter Name, DEA Number and Number of Prescriptions

Addendum 2: Universal Claim Form

DEPARTMENT OF HEALTH RELATED BOARDS - TENNESSEE BOARD OF PHARMACY
Controlled Substance Database
665 Mainstream Drive NASHVILLE, TENNESSEE 37243
(615) 253-1305 OR FAX (615) 253-8782

Universal Claim Form

Pharmacy DEA _____

Patient Details				
Last Name	**First Name**		**DOB**	**Gender**
Street Address	**City**		**State**	**Zip Code**
Prescriber Details				
Prescriber DEA #				
Prescription Details				
Prescription#	**Date Written**	**Total Number of Fills**	**Date Filled**	**Current Fill Number**
Product #(NDC)	**Final Qty.**	**Days Supply**	**Drug Dosage Unit**	**Payment Method**
Compound Ingredient Details-Only used if dispensing compound medications				
Ingredient#	**Prod#(NDC)**	**Drug Dosage Unit**	**Qty. of Controlled Substance**	

Patient Details				
Last Name	**First Name**		**DOB**	**Gender**
Street Address	**City**		**State**	**Zip Code**
Prescriber Details				
Prescriber DEA #				
Prescription Details				
Prescription#	**Date Written**	**Total Number of Fills**	**Date Filled**	**Current Fill Number**
Product #(NDC)	**Final Qty.**	**Days Supply**	**Drug Dosage Unit**	**Payment Method**
Compound Ingredient Details-Only used if dispensing compound medications				
Ingredient#	**Prod#(NDC)**	**Drug Dosage Unit**	**Qty. of Controlled Substance**	

Patient Details				
Last Name	**First Name**		**DOB**	**Gender**
Street Address	**City**		**State**	**Zip Code**
Prescriber Details				
Prescriber DEA #				
Prescription Details				
Prescription#	**Date Written**	**Total Number of Fills**	**Date Filled**	**Current Fill Number**
Product #(NDC)	**Final Qty.**	**Days Supply**	**Drug Dosage Unit**	**Payment Method**
Compound Ingredient Details-Only used if dispensing compound medications				
Ingredient#	**Prod#(NDC)**	**Drug Dosage Unit**	**Qty. of Controlled Substance**	

Addendum 3: Dispenser or Waiver Request

TENNESSEE DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
Controlled Substance Database Administrator
665 MAINSTREAM DRIVE
NASHVILLE, TENNESSEE 37243
(615) 253-1305 OR FAX (615) 253-8782

DISPENSER EXEMPTION OR WAIVER FROM ELECTRONIC REPORTING REQUEST

Please provide the information requested below. (Print or Type)

Name of Dispenser/Pharmacy:	Dispenser Regulatory Board License Number:
DEA Registration Number:	
Street Address:	City:
State: Zip:	Telephone Number: ( )
Name of Pharmacist in Charge:	Pharmacist in Charge TN License Number:
Signature:	Date:

"Dispense" means to physically deliver a controlled substance to any person, institution, or entity with the intent that it be consumed away from the premises in which it is dispensed. It does not include the act of writing a prescription by a practitioner to be filled at a pharmacy licensed by the board.

Justification for committee consideration of exemption from reporting:

☐ This dispenser does not hold a controlled substance registration with the Drug Enforcement Administration (DEA).

☐ This dispenser holds a DEA Registration but does not dispense any controlled substances.

☐ This dispenser is exempt from reporting according to T.C.A. 53-10-304(d) (Not required to report by alternate means)

- ☐ Drug is administered directly to a patient
- ☐ Drug is dispensed by a licensed healthcare facility or veterinarian in an amount to treat up to 48 hours maximum
- ☐ Dispensing drug samples
- ☐ Dispensing in a narcotic treatment program

Request for waiver of electronic reporting requirement: (must report by alternate means)

☐ This dispenser is applying for a waiver from electronic reporting authorized by Rule 1140-11-04(7) or T.C.A 53-10-305(g)(1)(A).

☐ This dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the "ASAP Telecommunications Format for Controlled Substances".
(Must report by alternate means)

☐ Electronic reporting would cause undue hardship (attach explanation).
(Must report by alternate means)

For Department Use Only

Date Received	☐ **Approved** ☐ **Disapproved**	**Director or Designee Signature**	**Date of Notification**

PH-4138 RDA 10146rev. 05/13

Addendum 4: Correcting/Deleting a Previously Submitted Prescription

Correcting/Deleting a Previously Submitted Prescription:

There are two ways of deleting/correcting a prescription once it has been accepted by the Data Collection Portal:

1. Create an ASAP 4.1 (2009) file with the prescriptions marked as either "revise" or "void," and submit the newly created file to the Data Collection Portal.
2. Delete/correct the prescription through the "Prescription Maintenance" portion of the Data Collection Portal (only available to pharmacies/dispensers who have a "Pharmacy" account, not available through a "FTP-Up-Loader" account.*)

*If a pharmacy submits files through an "FTP-Up-Loader" account, we can create a "Pharmacy" account that is linked to their DEA number, which will allow the pharmacy to use the "Prescription Maintenance" function.

ASAP Correction/Deletion File

A pharmacy can create a new ASAP 4.1 (2009) file and mark a previously submitted prescription as either "revise" or "void." The DSP01 field handles this by using the codes "01" for "revise" and "02" for "void" (this is all part of the ASAP Standard set by the American Society for Automation in Pharmacy.)

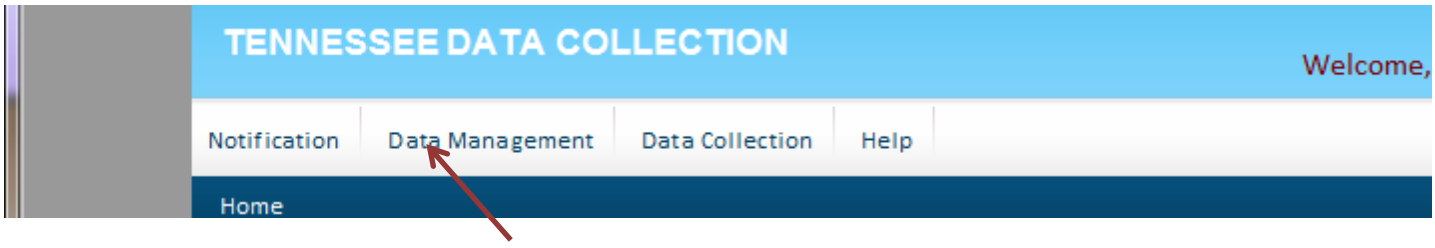
This would be a function of the pharmacy software* used by the individual pharmacy. The pharmacy will need to contact their software vendor for instructions on how to build this type of file within their particular software. Once the file has been created the pharmacy would upload the file to Optimum as though they were uploading a normal prescription file.

*There is no guarantee that all pharmacy software vendors provide this function as part of their package. It varies by Software Company.

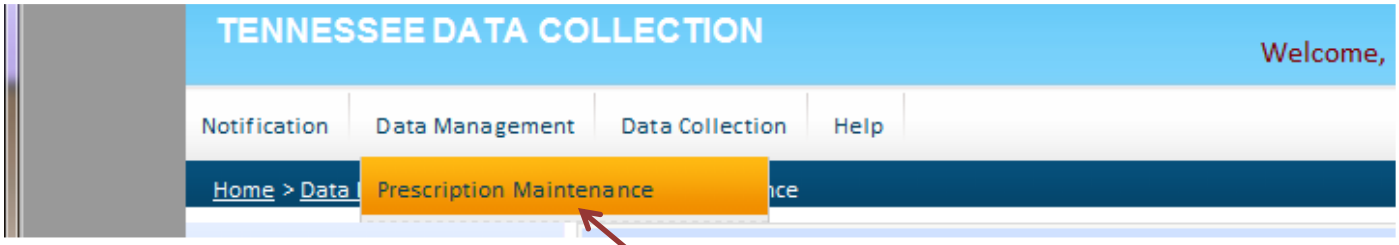
Prescription Correction through the Data Collection Portal

If a pharmacy wishes to correct a previously submitted prescription through the data collection portal, they will need use the following steps:

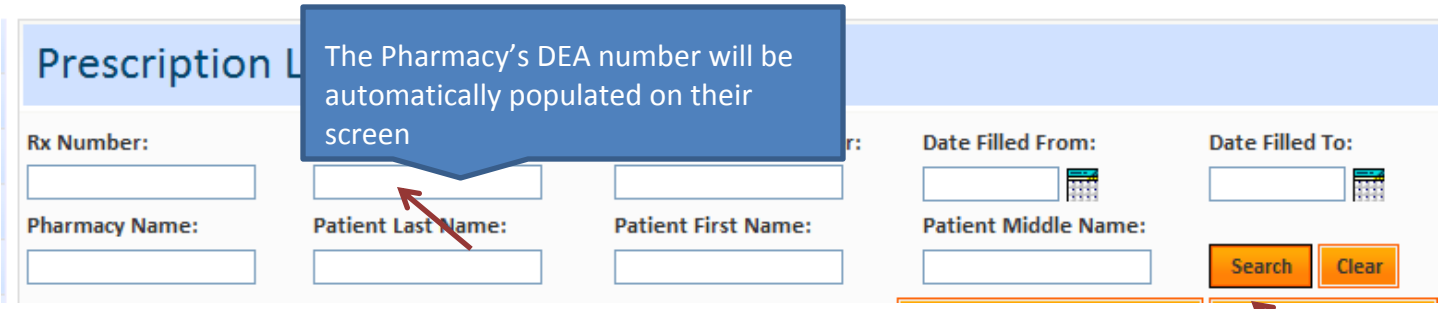
1. Log into their "Pharmacy" account (an "FTP-Up-Loader account does not have this function)
2. Hover over the "Data Management" tab near the upper left hand corner:



3. A dropdown menu will appear, click on “Prescription Maintenance”

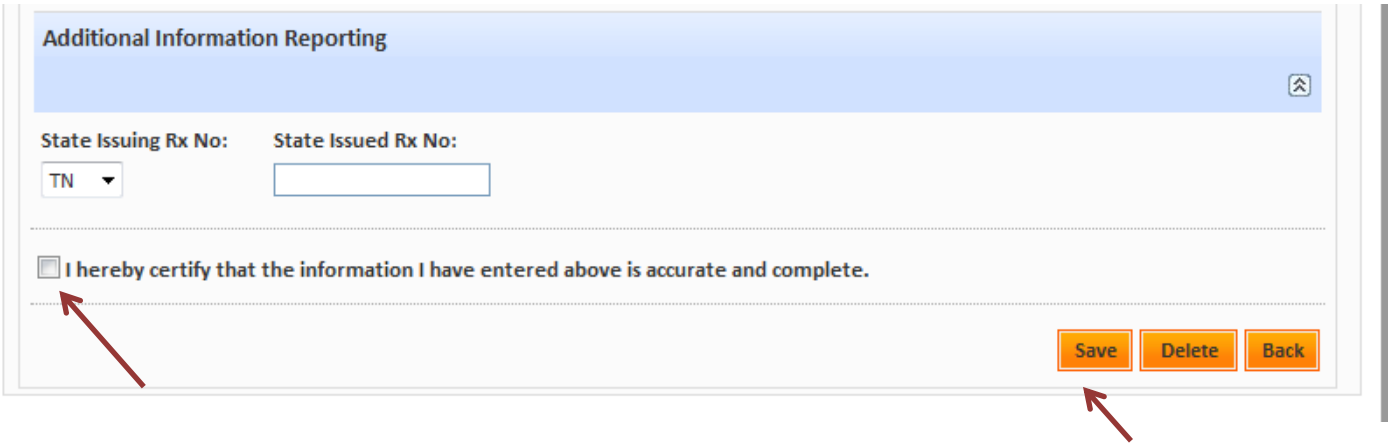


4. The pharmacy’s DEA number will be automatically populated in the “Prescription List.” From here the pharmacy can enter a variety of search criteria (e.g. patient name or prescription number) in order to find the prescription they wish to correct. Once the pharmacy has entered their search criteria click “search.” If the pharmacy wishes to see all of their submitted prescriptions, they would just click “search” without any additional criteria.



5. The resulting list can be sorted by RxNumber, Date Filled, Date Written, Patient First Name or Patient Last name in either ascending or descending order.
6. To see the prescription details, the pharmacy will need to click on the prescription number.

7. From the “Prescription Details” page the pharmacy can correct any of the required fields. To save the corrected information, the pharmacy will need to click the box next to the statement “I hereby certify that the information I have entered above is accurate and complete” at the bottom of the page. Once the authorization box has been checked, they must click the orange “Save” button.



8. Once they click the “Save” button, they will receive a message either stating that the prescription has been saved successfully, or if there is invalid information preventing the prescription from being saved

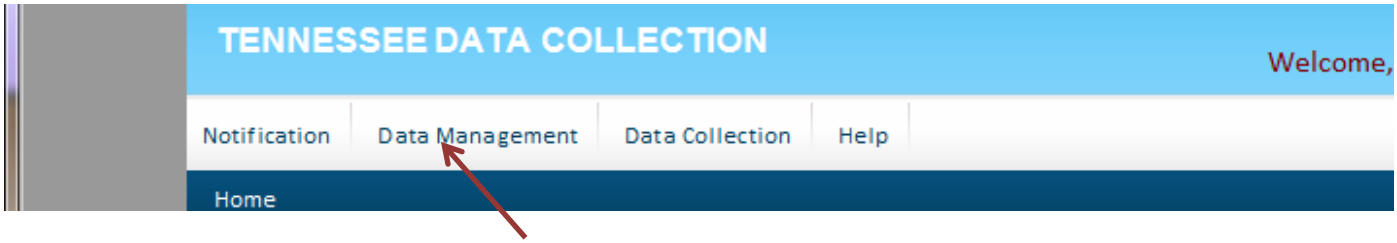
(Example: If the pharmacy entered an invalid prescriber DEA number, they would receive a message stating “Invalid DEA Number,” they would just need to retype the DEA number, and click “save.”)

9. Once the prescription has been saved, no further steps are required.

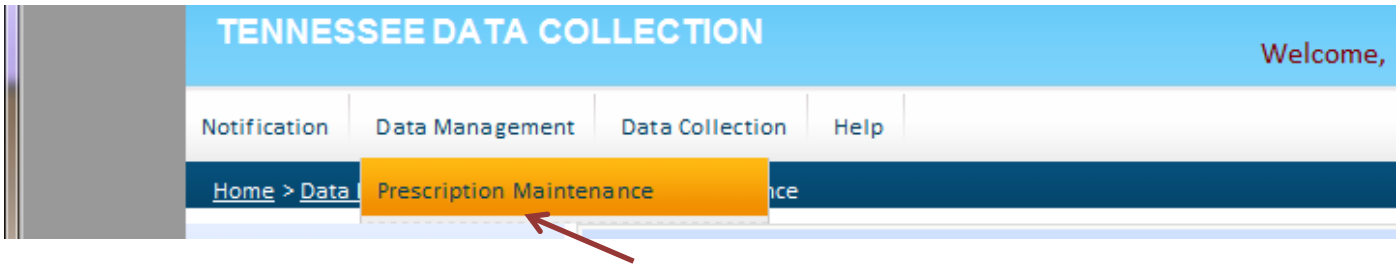
Prescription Deletion through the Data Collection Portal

If a pharmacy wishes to correct a previously submitted prescription through the data collection portal, they will need use the following steps:

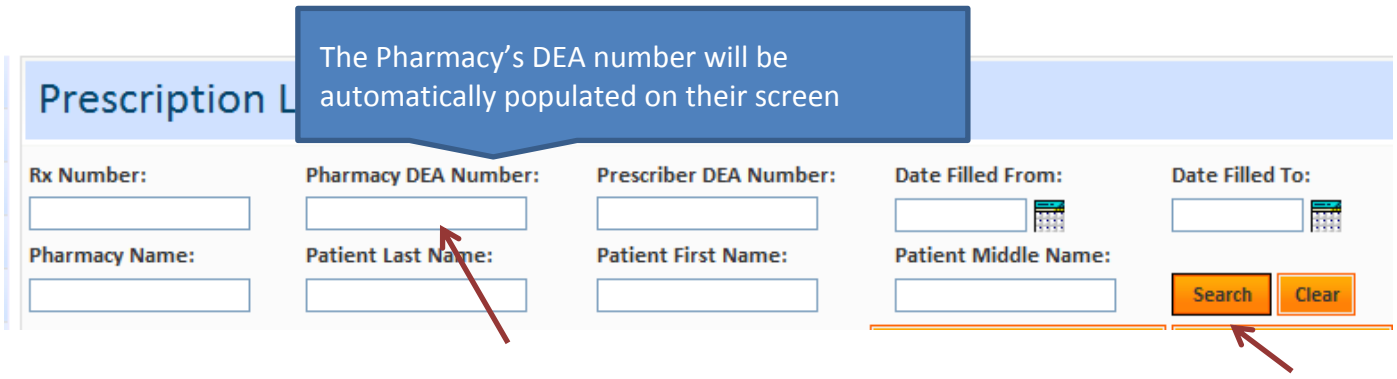
1. Log into their “Pharmacy” account (an “FTP-Up-Loader account does not have this function.)
2. Hover over the “Data Management” tab near the upper left hand corner.



3. A dropdown menu will appear, click on “Prescription Maintenance”

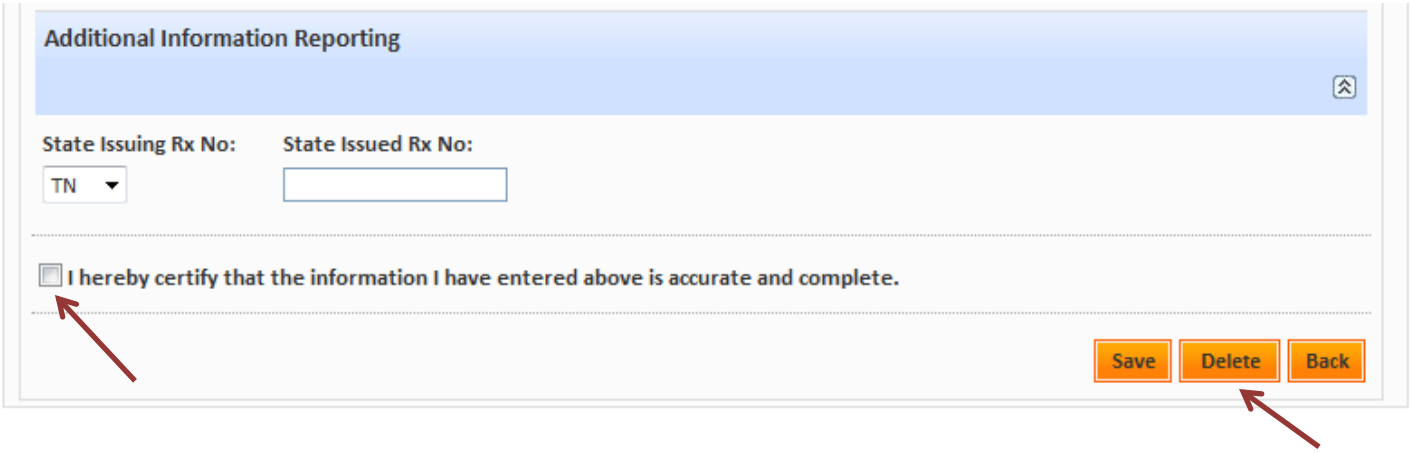


4. The pharmacy’s DEA number will be automatically populated in the “Prescription List.” From here the pharmacy can enter a variety of search criteria (e.g. patient name or prescription number) in order to find the prescription they wish to correct. Once the pharmacy has entered their search criteria click “search.” If the pharmacy wishes to see all of their submitted prescriptions, they would just click “search” without any additional criteria.



5. The resulting list can be sorted by: RxNumber, Date Filled, Date Written, Patient First Name or Patient Last name in either ascending or descending order.
6. To see the prescription details, the pharmacy will need to click on the prescription number.

7. From the "Prescription Details" page, the pharmacy will need to click the box next to the statement "I hereby certify that the information I have entered above is accurate and complete" at the bottom of the page. Once the authorization box has been checked, they must click the orange "Delete Button."



8. Once the prescription has been deleted they will receive a message at the top of the page stating that the prescription has been successfully deleted.
9. No further steps are required by the pharmacy once the prescription has been deleted.

Addendum 5: Zero Report

Prescription Monitoring Program Zero Reports - Summary of Required Data Elements

Ref. Code	Data Element Name	Format	Attributes*
TH TRANSACTION HEADER – (TH01-TH09)			Required Data
TH01	Version/Release Number	4.1	Yes
TH02	Transaction Control Number	See TT01; GUID is recommended	Yes
TH05	Created Date	CCYYMMDD	Yes
TH06	Creation Time	HHMMSS or HHMM	Yes
TH07	File Type	P = Production; T = Test	Yes
TH09	Segment Terminator Character	Examples: ~~ or || or ::	Yes
IS INFORMATION SOURCE – (IS01-IS03)			
IS01	Unique Information Source	Phone Number	Yes
IS02	Information Source Entity Name	Pharmacy Name	Yes
ISO3	Message: Free Form	Date Range of Zero Report: #CCYYMMDD#-#CCYYMMDD#	Yes
PHA DISPENSING PHARMACY – (PHA01-PHA12)			
PHA03	DEA Number		Yes
PAT - PATIENT DETAIL SEGMENT – (PAT01-PAT23)			
PAT07	Last Name	Zero	Yes
PAT08	First Name	Report	Yes
DSP - DISPENSING DETAIL SEGMENT - REQUIRED			
DSP05	Date Filled	Date submitted: CCYYMMDD	Yes
TP - PHARMACY TRAILER – REQUIRED			
TP01	Detail Segment Count	Includes PHA; all Detail segments & TP segment	Yes
TT01	Transaction Control Number	Must match TH02	Yes

Ref. Code	Data Element Name	Format	Attributes*
TT02	Segment Count	Total # of segments, including header and trailer segments	Yes

Example ASAP zero report for Jan 01, 2013 to Jan 15, 2013:

TH*4.1*1700121700*01**20130116*1700*P**\\
IS*Phone Number*Pharmacy Name*#20130101#-#20130115#\
PHA***AB1234567\
PAT*******Report*Zero\
DSP*****20130116*\
PRE**\
TP*5\
TT*1700121700*8\